K072688

Section 5. 510 (K) Summary

Non Confidential Summary of Safety and Effectiveness

Submitter Information:

International Biophysics Corporation (IBC)
2101 East St. Elmo Rd, Suite 275
Austin, TX 78744

Contact:

David Shockley
President
512-326-3244 off.
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JAN 1 [illegible]

Date Prepared: September 19, 2007

Proprietary Name: LifeChoice Oxygen Concentrator

Model: OXY1000

Classification Name: Portable oxygen generator (concentrator)

Product Code: CAW

Device Classification: Class II

Panel: Anesthesiology

Regulation Number: 21 CFR 868.5440

Predicate Device: AirSep Corporation, LifeStyle Oxygen Concentrator, 510(K): K020324

Device Description:

The IBC LifeChoice Oxygen Concentrator is a prescription use device for patients needing supplemental high concentration oxygen. The LifeChoice is not intended to be life sustaining or to be life supporting. The LifeChoice provides approximately 90% oxygen to the patients on a demand flow basis at an equivalent rate of 1.0 liter per minute to 3.0 liters per minute in increments of 1.0 liter per minute. The LifeChoice is a portable device which may be used continuously in a home, institution or travel environment.

The LifeChoice uses molecular sieve pressure swing adsorption technology. This technology is well established and proven to concentrate room air into high concentration oxygen. The LifeChoice is equivalent in performance, function and principles of operation to the predicate device listed in this submission.

Indications for Use:

The LifeChoice Oxygen Concentrator is used on a prescriptive basis by patients who are diagnosed as requiring supplemental oxygen. This oxygen concentrator will provide supplemental, high concentration oxygen to these patients. It is not life supporting nor life sustaining. It may be used continuously in a home, institution or travel environment. The LifeChoice is also portable.

Technological Characteristics and Predicate Device Comparison:

The IBC LifeChoice Oxygen Concentrator utilizes well established technologies. Molecular sieve pressure swing adsorption technology has been used for many years to produce high concentration oxygen. Demand flow delivery systems have been in use on portable oxygen devices for many years also. The capability to power the device with AC, DC and/or rechargeable batteries has also been in use for many years.

The technologies used in the IBC LifeChoice Oxygen Concentrator do not create any new questions of safety and effectiveness. These technologies are also being used in the identified predicate device. Benchtop performance testing and comparison of performance characteristics and technologies have demonstrated that the IBC LifeChoice is substantially equivalent to the identified predicate device, the AirSep LifeStyle Oxygen Concentrator. There are no significant differences between the IBC LifeChoice and the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

Mr. David Shockley
President
International Biophysics Corporation
2101 East St. Elmo Road, Suite 275
Austin, Texas 78744

Re: K072688
Trade/Device Name: International Biophysics Corporation LifeChoice Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: January 3, 2008
Received: January 3, 2008

Dear Mr. Shockley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

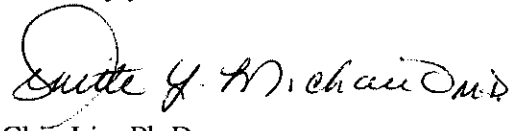
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K072688:

Device Name: International Biophysics Corporation LifeChoice Oxygen Concentrator

Indications For Use:

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Prescription use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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